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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/235,875	01/22/1999	LARA MADISON	MBX020	2296

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EXAMINER	
KALLIS, RUSSELL	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/235,875	MADISON ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,7,10,14 and 16-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,7,10,14 and 16-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/19/2000*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *PTOL 461 and 462*.

DETAILED ACTION

Rejection of Claims 1, 7, 10, 15, 18, 19 and 20 under 35 U.S.C. 102(b) is withdrawn in view of Applicant's amendments.

Rejection of Claims 1, 6, 7 and 14-21 under 35 U.S.C. 103(a) is withdrawn in view of Applicant's amendments.

Rejection of Claims 1, 6, 7, 10 and 14-21 under 35 U.S.C. 112, first paragraph, new matter is withdrawn in view of Applicant's amendments.

Rejection of Claims 1, 6, 10 and 16 under obvious double patenting is withdrawn in view of Applicant's filing of terminal disclaimers.

Claims 2-5, 8-9, 11-13, 15 and 22-34 are canceled. Claims 1, 6-7, 10, 14 and 16-21 are pending and examined.

Specification

The disclosure is objected to because of the following informalities: On page 19, lines 20-21 contain an incomplete reference. The Examiner believes that the reference is to Herrero *et al.* J. of Bacteriology, November 1990; Vol. 172, No. 11, pp. 65570-6567. Applicant should state the complete bibliographic reference.

Appropriate correction is required.

Claim Objections

Claim 1 is objected to because of the following informalities: the use of "beta-"to define the substrate and products in lines 3 and 4 is inconsistent with the "3-" designation of substrates in lines 5 and 6. It is suggested that a standard chemical nomenclature be applied consistently over all the claims.

Claims 10, 16, 17 and 18 are objected to because of the following informalities: bacteria is the plural of "bacterium", the verb form should reflect that; i.e. "bacteria comprise" and "bacteria express".

Claims 7 and 14 are objected to because of the following informalities: "bacteria" should be "bacterium".

Claim 17 is objected to because of the following informalities: the limitations of "a PHB biosynthetic thiolase" in lines 1-2 is the same as both the "thiolase specific for 3-ketohexanoyl CoA recited in lines 2-3 of Claim 17 and the thiolase recited in Claim 1. Since Claim 1 already recites "a thiolase . . . that converts butyryl-CoA and acetyl CoA to beta-ketohexanoyl-CoA" which is the same as "a PHB biosynthetic thiolase", the redundant limitations should be deleted from Claim 17. Further, Claim 17 also recites "a reductase specific for 3-ketohexanoyl CoA" which is the same as the limitation of Claim 1 that recites "a reductase . . . that converts beta-ketohexanoyl-CoA to beta-ketohydroxyhexanoyl-CoA" and should be deleted from the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 16 and 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Fukui *et al.* (J. of Bacteriol. Vol. 179: 4821-4830, 1997).

Claims are drawn to a method for the biological production of polyhydroxyalkanoate containing 3-hydroxyhexanoate, comprising providing genetically engineered bacteria that express a thiolase gene, a reductase gene, and a PHA polymerase gene encoding an enzyme that polymerizes 3-hydroxybutyryl CoA and 3-hydroxyhexanoyl CoA; wherein the polymerase is from a bacterium selected from the group consisting of *Aeromonas caviae, C. testosterone, T. pfenigii, C. vinosum, B. cereus, N. Carolina, N. salmonicolor, R. rubber R. rhodocrous,* and *R. rubrum*; or the bacteria further expresses a gene encoding a D-specific enoyl-CoA hydratase; or the bacteria expresses one or more fatty acid biosynthetic enzymes.

Schubert P. *et al.*, (J. of Bacteriology 1988; Vol. 170, No. 12, p. 5837-5847) is provided as evidence in the discussion below.

Fukui discloses a method for producing polyhydroxyalkanoates containing 3-hydroxhexanoate by transformation of *Alacaligenes eutrophus (now called R. eutropha)* and *Pseudomonas putida* with a *phaC* gene from *Aeromonas caviae* encoding a PHA synthase (polymerase) that polymerizes polyhydroxybutyrate-co-3-hydroxyhexanoate (HB-co-3HH) when grown on hexanoate or octanoate; wherein levels of HB-co-3HHx polymer accumulated to 96% of total cellular dry weight when grown on octanoate and the mol fraction of HB and HHx in the co-polyester reached 80% HB and 20% HHx, and when grown on hexanoate polymer accumulated to 72% of total cellular dry weight and the mol fraction of HB and HHx in the co-polyester reached 50% (See Fukui abstract, especially the last 2 lines; page 4828 Table 3 see pJRDEE32d13, and page 4829 column 2, lines 37-42), and wherein *A. eutrophus* inherently comprises an endogenous thiolase gene (*phbA*), reductase gene (*phbB*), and a D-specific enoyl-CoA hydratase; and inherently expresses an acyl CoA synthase and a fatty acid biosynthetic

enzyme (See Schubert *et al.* page 5844 column 2 line 10 to page 5845 column 1 line 5 and enzyme number 6 in figure 2; see enzyme number 1 in figure 2); and thus the reference teaches all the limitations of Claims 1, 7, 16 and 18-21.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6-7, 16 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukui *et al.* (J. of Bacteriol. 1997; Vol. 179: p. 4821-4830), in view of Macharenas *et al.* (U.S. Patent 5,470,727 issued 28 November 1995); in further view of Schubert P. *et al.*, (J. of Bacteriology 1988; Vol. 170, No. 12, p. 5837-5847).

The claims are broadly drawn to a method for the biological production of polyhydroxyalkanoate containing 3-hydroxyhexanoate in genetically engineered bacteria expressing a *phbA* thiolase gene, a *phbB* reductase gene, and a gene encoding a *PHA* polymerase that polymerizes 3-hydroxybutyryl CoA and 3-hydroxyhexanoyl-CoA to produce polyhydroxybutyrate-co-3-hydroxyhexanoate; wherein the PHA polymerase transgene is incorporated into the bacterial chromosomal DNA; wherein the bacteria express a gene encoding a D-specific enoyl-CoA hydratase and one or more fatty acid biosynthetic enzymes.

Fukui discloses a method for producing polyhydroxyalkanoates containing 3-hydroxhexanoate by transformation of *Alacaligenes eutrophus (now called R. eutropha)* and *Pseudomonas putida* with a *phaC* gene from *Aeromonas caviae* encoding a PHA synthase

(polymerase) that polymerizes polyhydroxybutyrate-co-3-hydroxyhexanoate (HB-co-3HH) when grown on hexanoate or octanoate; wherein levels of HB-co-3HHx polymer accumulated to 96% of total cellular dry weight when grown on octanoate and the mol fraction of HB and HHx in the co-polyester reached 80% HB and 20% HHx, and when grown on hexanoate polymer accumulated to 72% of total cellular dry weight and the mol fraction of HB and HHx in the co-polyester reached 50% (See Fukui abstract, especially the last 2 lines; page 4828 Table 3 see pJRDEE32d13, and page 4829 column 2, lines 37-42).

Fukui does not teach a method of making polyhydroxyalkanoate wherein the *PHA* polymerase (synthase) gene is incorporated into the bacterial chromosome.

Mascarenhas teaches that chromosomal integration of genes encoding heterologous peptides would be advantageous as an alternative means for expression of foreign proteins in bacterial host cells because plasmids or multi copy vectors are unstable and require some means of selection such as antibiotics in order to maintain their expression (see column 1, lines 10-32) and also teaches a method of chromosomal integration of a foreign gene (see the Example in columns 7 and 8; and Claim 1).

Schubert teaches that *A. eutrophus* comprises an endogenous thiolase gene (*phbA*), reductase gene (*phbB*), and a D-specific enoyl-CoA hydratase; and also expresses an endogenous acyl CoA synthase and a fatty acid biosynthetic enzyme; (See Schubert *et al.* page 5844 column 2 line 10 to page 5845 column 1 line 5 and enzyme number 6 in figure 2; see enzyme number 1 in figure 2).

It would have been obvious to modify the invention of Fukui to substitute the expression of a foreign gene on a plasmid for the expression of the foreign gene from the bacterial

chromosome as taught by Mascarenhas. One of ordinary skill in the art would have recognized what is generally known in the art, that plasmid based bio-reactor systems require an extra burden of maintaining the plasmid under selection and the problem of stable expression, as well as plasmid maintenance, could be overcome by using chromosomally integrated genes and one of ordinary skill would have been motivated by the teachings of Mascarenhas that chromosomal integration of foreign genes into the bacterial chromosome would allow for stable expression of a recombinant protein without maintaining selection; and by the knowledge that *A. eutrophus* comprises an endogenous thiolase gene (*phbA*), reductase gene (*phbB*), a D-specific enoyl-CoA hydratase gene and an acyl CoA synthase gene already integrated into the chromosome; (See Schubert *et al.* page 5844 column 2 line 10 to page 5845 column 1 line 5 and enzyme number 6 in figure 2; see enzyme number 1 in figure 2); and further motivated by the success of Fukui in producing polyhydroxybutyrate-co-3-polyhydroxyhexanoate from *A. eutrophus* and *Pseudomonas putida* transformed only with the *PHA* synthase gene from *A. eutrophus* (now called *R. eutropha*) wherein levels of HB-co-3HHx polymer accumulated to 96% of total cellular dry weight and the mol fraction of HHx in the co-polyester reached 50% when grown on octanoate or hexanoate (See abstract especially the last 2 lines; and page 4829 column 2, lines 37-42); and the success of Mascarenhas in stably expressing chromosomally integrated foreign genes; and that one of ordinary skill would have a reasonable expectation of success given the success of Fukui and Mascarenhas.

Claims 1, 7, 10 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Timm A. *et al.* (Applied and Environmental Microbiology, November 1990, Vol. 56, No. 11, p. 3360-3367) in view of Fukui *et al.* (J. of Bacteriol. 1997; Vol. 179: p. 4821-4830) and in further view of Hoffman N. *et al.* (FEMS Microbiology Letters, 2000, p. 253-259).

The claims are broadly drawn to a method for the biological production of polyhydroxyalkanoate containing 3-hydroxyhexanoate in genetically engineered bacteria expressing a *phbA* thiolase gene, a *phbB* reductase gene, and a gene encoding a *PHA* polymerase that polymerizes 3-hydroxybutyryl CoA and 3-hydroxyhexanoyl-CoA to produce polyhydroxybutyrate-co-3-hydroxyhexanoate; wherein the bacteria further comprises a gene encoding beta-hydroxyacyl-ACP-coenzyme transferase (claim 10).

Timm teaches *Pseudomonas aeruginosa* transformed with the *PHB* synthetic genes comprising a thiolase gene (*phbA*), a reductase gene (*phbB*), and a polymerase gene (*phbC*) from *A. eutrophus (now called R. eutropha)*, that produced a polymer that consisted 37.5 mol% 3-hydroxybutyrate, 2.1 mol% 3-hydroxyhexanoate, 57.7 mol% 3-hydroxyoctanoate, and 2.7 mol% 3-hydroxydodecanoate (see page 3362, column 2 results section 1st and 2nd paragraphs); and wherein *Pseudomonas aeruginosa* comprises an endogenous native *phaG* gene (i.e. a gene encoding a β-hydroxyacyl-ACP-coenzyme A transferase) also known as an ACP-CoA acyltransacylase (see title and abstract of Hoffmann) and expresses one or more fatty acid biosynthetic enzymes.

Timm does not teach transformation with a PHA polymerase gene *(phaC)*.

Fukui discloses a method for producing polyhydroxyalkanoates containing 3-hydroxhexanoate by transformation of *Alacaligenes eutrophus (now called R. eutropha)* and

Pseudomonas putida with a *phaC* gene from *Aeromonas caviae* encoding a PHA synthase (polymerase) that polymerizes polyhydroxybutyrate-co-3-hydroxyhexanoate (HB-co-3HH) when grown on hexanoate or octanoate; wherein levels of HB-co-3HHx polymer accumulated to 96% of total cellular dry weight when grown on octanoate and the mol fraction of HB and HHx in the co-polyester reached 80% HB and 20% HHx, and when grown on hexanoate polymer accumulated to 72% of total cellular dry weight and the mol fraction of HB and HHx in the co-polyester reached 50% (See Fukui abstract, especially the last 2 lines; page 4828 Table 3 see pJRDEE32d13, and page 4829 column 2, lines 37-42).

Hoffmann teaches that *Pseudomonas aeruginosa* comprises an endogenous gene encoding a beta-hydroxyacyl-ACP-coenzyme A transferase (see abstract).

It would have been obvious to modify the invention of Timm by substituting the PHA polymerase gene taught by Fukui to further enhance the production of HB-co-3HHx polymer and to increase the mol fraction of HHx in the co-polymer. One of ordinary skill would have been motivated by the apparently high specificity for 3-hydroxyhexanoyl-CoA of the PHA polymerase from *A. caviae* that resulted in not only a 96% or 72% of total dry weight for the HB-co-3HHx copolymer, but also that the mol fraction of HHx in the co-polyester was 20% or as high as 50% and recognized that the endogenous beta-hydroxyacyl-ACP-coenzyme A transferase gene of *Pseudomonas aeruginosa* encodes an enzyme that strongly enhances the metabolic flux from fatty acid biosynthesis to the production of HB-co-3HHx polymer and would have had a reasonable expectation of success in transforming *P. aeruginosa* with a PHA polymerase that polymerizes polyhydroxybutyrate-co-3-hydroxyhexanoate and increased the production of HB-co-3HHx polymer.

Claims 1, 7, 14 and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schubert P. *et al.*, (J. of Bacteriology 1988; Vol. 170, No. 12, p. 5837-5847) in view of Fukui *et al.* (J. of Bacteriol. Vol. 179: 4821-4830, 1997) in further view of Boynton Z. *et al.* (J. of Bacteriology June 1996, Vol. 178, No. 11, p. 3015-3024) and Feigenbaum J, *et al.* (PNAS, February 1977; Vol. 74, No. 2, pp. 492-495).

The claims are broadly drawn to a method for the biological production of polyhydroxyalkanoate containing 3-hydroxyhexanoate, comprising providing genetically engineered bacteria that express a thiolase gene, a reductase gene, and a PHA polymerase gene encoding an enzyme that polymerizes 3-hydroxybutyryl CoA and 3-hydroxyhexanoyl CoA; wherein the bacteria is *E. coli*.

Schubert teaches the production of PHB (polyhydroxybutyrate) in *E. coli* transformed with a thiolase gene (*phbA*), a reductase gene (*phbB*), and a polymerase gene (*phbC*) isolated from *A. eutrophus*, and further teaches pathways that feed hydroxybutyryl-CoA substrate to a PHA polymerase comprising three enzymes that form butyryl CoA and a D-specific enoyl-CoA hydratase (page 5845, figure 2; especially the 3 enzymes of number 8; page 5844, column 2 line 36 to page 5845 column 1 line 5; and enzyme number 6 in figure 2).

Schubert does not teach *E. coli* transformed with a PHA polymerase gene *(phaC)*.

Fukui discloses a method for producing polyhydroxyalkanoates containing 3-hydroxhexanoate by transformation of *Alacaligenes eutrophus (now called R. eutropha)* and *Pseudomonas putida* with a *phaC* gene from *Aeromonas caviae* encoding a PHA synthase (polymerase) that polymerizes polyhydroxybutyrate-co-3-hydroxyhexanoate (HB-co-3HH) when grown on hexanoate or octanoate; wherein levels of HB-co-3HHx polymer accumulated to 96%

of total cellular dry weight when grown on octanoate and the mol fraction of HB and HHx in the co-polyester reached 80% HB and 20% HHx, and when grown on hexanoate polymer accumulated to 72% of total cellular dry weight and the mol fraction of HB and HHx in the co-polyester reached 50% (See Fukui abstract, especially the last 2 lines; page 4828 Table 3 see pJRDEE32d13, and page 4829 column 2, lines 37-42).

Boynton teaches three enzymes from *C. acetobutylicum* that form butyryl CoA transformed into *E. coli* and *A. acetobutylicum* (see abstract).

Feigenbaum teaches a thiolase expressed in *E. coli* that has specificity for 3-ketohexanoyl CoA (see page 492 column 2 lines 10-16; especially line 15).

It would have been obvious to modify the method of producing polyhydroxybutyrate in transformed *E. coli* of Schubert, comprising recombinant thiolase (*phbA*), reductase (*phbB*) and (*phbC*) polymerase genes, to substitute a PHA polymerase gene *(phaC)* from *A. eutrophus* taught by Fukui that recognizes a broader range of substrates to produce polyhydroxybutyrate-co-3-polyhydroxyhexanoate when grown on octanoate or hexanoate; one of ordinary skill in the art would have been motivated by the success of Fukui of producing polyhydroxyalkanoates containing 3-hydroxhexanoate in *A. eutrophus* that comprised 96% of the total cellular dry weight when transformed with a gene encoding a PHA polymerase that has a specificity for 3-hydroxyhexanoyl-CoA and would have recognized the value of the teachings of Fukui to the art of manufacturing PHA polymers comprising 3-hydroxyhexanoate as a co-polymer; that the composition of the growth medium in combination with the PHA synthase and the endogenously expressed thiolase and reductase genes of *A. eutrophus* is sufficient for 3HB-co-3HHx production. One of ordinary skill would have been further motivated by the success of Schubert

in producing polyhydroxyalkanoate up to 30% of cellular dry weight in *E. coli* a bacteria that does not normally produce PHA polymers, and recognized the value of the teachings of Schubert that there are several pathways in *A. eutrophus* that can feed beta-hydroxybutyryl-CoA substrate to a PHA synthase or polymerase by means of a fatty acid degradation pathway comprising three enzymes that form butyryl-CoA and an enoyl-COA hydratase (see page 5845, figure 2; especially the 3 enzymes of number 8 and enzyme number 6); and recognized the value of the teachings of Boynton who showed expression of the three fatty acid degrading enzymes from *C. acetobutylicum* that form butyryl-CoA in transformed bacteria; and that one of ordinary skill would have a reasonable expectation of success of producing polyhydroxybutyrate-co-3-hydroxyhexanoate given the success of Schubert in producing PHB polymers in *E. coli* up to 30% dry weight by expressing the PHA biosynthetic genes comprising a thiolase, a reductase and a PHB polymerase and by the success of Fukui in demonstrating the production of polyhydroxybutyrate-co-3-hydroxyhexanoate up to 96% cellular dry weight by transforming the bacterium *A. eutrophus* with only the PHA synthase and that further including the three enzymes that form butyryl CoA and the thiolase that accepts 3-keto hexanoyl-CoA or the D-specific enoyl-CoA hydratase as taught by Schubert's scheme of providing substrate to the polymerase is an obvious optimization of design parameters that would only further enhance the expectation of success in producing polyhydroxybutyrate-co-polyhydroxyhexanoate in genetically engineered bacteria.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
January 26, 2006

RUSSELL P. KALLIS, PH.D.
PATENT EXAMINER

JASEMINE C. CHAMBERS
DIRECTOR
TECHNOLOGY CENTER 1600

Communication Re: Appeal	Application No.	Applicant(s)	
	09/235,875	MADISON ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

1. ☒ The Notice of Appeal filed on *19 January 2006* is not acceptable because:

   (a) ☐ it was not timely filed.

   (b) ☐ the statutory fee for filing the appeal was not submitted. See 37 CFR 41.20(b)(1).

   (c) ☐ the appeal fee received on _____ was not timely filed.

   (d) ☐ the submitted fee of $_____ is insufficient. The appeal fee required by 37 CFR 41.20(b)(1) is $_____.

   (e) ☐ the appeal is not in compliance with 37 CFR 41.31(a)(1) in that no claim has been twice rejected.

   (f) ☐ a Notice of Allowability, PTO-37, was mailed by the Office on _____.

2. ☐ The appeal brief filed on _____ is NOT acceptable for the reason(s) indicated below:

   (a) ☐ the brief and/or brief fee is untimely. See 37 CFR 41.37(a).

   (b) ☐ the statutory fee for filing the brief has not been submitted. See 37 CFR 41.20(b)(2).

   (c) ☐ the submitted brief fee of $_____ is insufficient. The brief fee required by 37 CFR 41.20(b)(2) is $_____.

The appeal in this application will be dismissed unless corrective action is taken to timely submit the brief and requisite fee. See 37 CFR 41.37(a)(1). Extensions of time may be obtained under 37 CFR 1.136(a). See 37 CFR 41.37(e).

3. ☒ The appeal in this application is DISMISSED because:

   (a) ☐ the statutory fee for filing the brief as required under 37 CFR 41.20(b)(2) was not timely submitted and the period for obtaining an extension of time to file the brief under 37 CFR 1.136(a) has expired.

   (b) ☐ the brief was not timely filed and the period for obtaining an extension of time to file the brief under 37 CFR 1.136(a) has expired.

   (c) ☐ a Request for Continued Examination (RCE) under 37 CFR 1.114 was filed on _____.

   (d) ☒ other: *See Continuation Sheet.*

4. ☒ Because of the dismissal of the appeal, this application:

   (a) ☐ is abandoned because there are no allowed claims.

   (b) ☐ is before the examiner for final disposition because it contains allowed claims. Prosecution on the merits remains CLOSED.

   (c) ☒ is before the examiner for consideration.

Continuation of 3. (d) Other: Issues newly raised by the Examiner in response to the amendment filed 11/17/2005 are addressed in the attached Office action. Applicant filed a reply under 37 CFR 1.111 rather than only appealing from the second non-final rejection, the notice of appeal is premature for the following reasons: 1) The Office has not had the opportunity to consider the reply under 37 CFR 1.111 and issue an Office action in view of the reply (note that this is different than after-final situations where a reply under 37 CFR 1.116 is not entered as matter of right and applicant is appealing from the final rejection); 2) The status of the claims are uncertain as to whether the examiner would reject the claims again in view of the reply (e.g. the appeal would be unneccesary if the reply places the claims in condition for allowance); 3) The grounds of rejection are uncertain as to whether the examiner would apply the same grounds of rejection made in the second non-final rejection or make a new ground of rejection with or without using a new prior art reference; 4) It is unclear which "decision" by the examiner applicant is appealing from because the second non-final rejection may no longer be relevant in view of the reply under 37 CFR 1.111; and 5) A two month time period for filing an appeal brief cannot be running against applicant when applicant cannot determine whether the claims are under rejction again and which grounds of rejection would apply to the claims. Accordingly, since the filing of the appeal brief after a reply under 37 CFR 1.111 but before the Office issues another Office action in view of the reply, the notice of appeal is filed prematurely, and is thus defective. Applicant must wait to file any appeal until the examiner considers the reply and the claims are rejected again. Once the Office action mailed in response to the reply applicant may file another notice of appeal under 37 CFR 41.31. Any previously paid fees for the first notice of appeal will be applied to the new notice of appeal. If however, the appeal fee has increased, applicant is required to pay the difference between the current fee and the amount previously paid at the time of filing the second notice of appeal. Any patent term adjustment determination for a successful appellate review will begin on the date of the new notice of appeal and not on the date of the defective notice of appeal.

Notification of Non-Compliant Appeal Brief (37 CFR 41.37)	Application No. 09/235,875	Applicant(s) MADISON ET AL.	
	Examiner Russell Kallis	Art Unit 1638	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The Appeal Brief filed on *19 January 2006* is defective for failure to comply with one or more provisions of 37 CFR 41.37.

To avoid dismissal of the appeal, applicant must file anamended brief or other appropriate correction (see MPEP 1205.03) within **ONE MONTH or THIRTY DAYS** from the mailing date of this Notification, whichever is longer. **EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136.**

1. ☐ The brief does not contain the items required under 37 CFR 41.37(c), or the items are not under the proper heading or in the proper order.

2. ☐ The brief does not contain a statement of the status of all claims, (e.g., rejected, allowed, withdrawn, objected to, canceled), or does not identify the appealed claims (37 CFR 41.37(c)(1)(iii)).

3. ☐ At least one amendment has been filed subsequent to the final rejection, and the brief does not contain a statement of the status of each such amendment (37 CFR 41.37(c)(1)(iv)).

4. ☐ (a) The brief does not contain a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number and to the drawings, if any, by reference characters; and/or (b) the brief fails to: (1) identify, for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function under 35 U.S.C. 112, sixth paragraph, and/or (2) set forth the structure, material, or acts described in the specification as corresponding to each claimed function with reference to the specification by page and line number, and to the drawings, if any, by reference characters (37 CFR 41.37(c)(1)(v)).

5. ☐ The brief does not contain a concise statement of each ground of rejection presented for review (37 CFR 41.37(c)(1)(vi))

6. ☐ The brief does not present an argument under a separate heading for each ground of rejection on appeal (37 CFR 41.37(c)(1)(vii)).

7. ☐ The brief does not contain a correct copy of the appealed claims as an appendix thereto (37 CFR 41.37(c)(1)(viii)).

8. ☐ The brief does not contain copies of the evidence submitted under 37 CFR 1.130, 1.131, or 1.132 or of any other evidence entered by the examiner **and relied upon by appellant in the appeal**, along with a statement setting forth where in the record that evidence was entered by the examiner, as an appendix thereto (37 CFR 41.37(c)(1)(ix)).

9. ☐ The brief does not contain copies of the decisions rendered by a court or the Board in the proceeding identified in the Related Appeals and Interferences section of the brief as an appendix thereto (37 CFR 41.37(c)(1)(x)).

10. ☒ Other (including any explanation in support of the above items):

The double patenting rejections have not yet been withdrawn and should be formally addressed in the appeal brief. Further, Claim 15 has been cancelled, yet it appears in the grounds for rejection under 102(b) (see pages 4 and 11 of the file appeal brief).